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10/057,630	01/25/2002	**Ronald M. Burch**	200.1079CON5	3300

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Davidson, Davidson & Kappel, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	**PAPER NUMBER**
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/057,630	BURCH ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. GROSS	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38 and 47-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38 and 47-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 2/26/2008;6/26/2008;11/5/2008. Claims 38,47-68 are pending. Claims 38,47-68 are under consideration.

Election/Restrictions

Applicant's election without traverse of: alkylcellulose for the species of sustained release carrier; arthritis for the species of pain; a tablet with a diameter about 0.5 mm to about 2 mm with a sustained release carrier being incorporated into a matrix with oxycodone for the species of tablet formulation the reply filed on 6/26/2008 is acknowledged.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 or 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The instant application, filed 1/25/2002 claims priority as a CON of application 09/154,354 09/17/1998 (now PAT 6,552,031) which claims benefit of provisional application 60/059,195 filed 09/17/1997.

Nevertheless the following limitations are not disclosed in the earlier applications.

1. a method for effectively treating pain in humans with an oral dosage consisting of nimesulide, oxycodone and a pharmaceutically acceptable excipient (amended claim 38).

2. a pharmaceutically acceptable salt of oxycodone in a sustained release form (new claims 54,65).

3. a therapeutic effect using oxycodone at least 12 hours or longer (new claim 55).

4. a pharmaceutically acceptable salt of oxycodone with a sustained release carrier such as alkylcellulose (new claim 56).

5. a method of effectively treating pain such as from arthritis using pharmaceutically acceptable salt of oxycodone in a sustained release form (new claims 57,67-68)

6. dosage forms using a pharmaceutically acceptable salt of oxycodone in a sustained release form with particles from about 0.1 mm to about 2.5 mm or from about 0.1 mm to about 2.5 mm (new claims 58-59).

7. nimusilide being coated onto a tablet comprising oxycodone plus a sustained release carrier (new claim 60).

8. a sustained release carrier incorporated into a matrix with oxycodone (new claim 61).

9. a therapeutic effect using oxycodone for 24 hours (new claim 62).

10. a method for effectively treating pain in humans with an oral dosage consisting of nimesulide plus a salt thereof, oxycodone plus a pharmaceutically acceptable salt thereof plus a pharmaceutically acceptable excipient (new claim 63).

11. sustained release of nimesulide (new claim 66).

None of the above limitations are disclosed in the earlier applications, especially with regard to oxycodone. See also 35 USC 112 first paragraph rejection below concerning "new matter."

If applicant believes this assessment is in error, applicant is to indicate as to page and line where support for each of the above limitations may be found in the earlier applications.

Therefore 1/25/2002 is the date for the purposes of prior art concerning claims 38,47-68.

Withdrawn Objection(s) and/or Rejection(s)

The rejection of claims 38, 47-48, 50-53 under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,569,937 (Baker et al) and Swingle et al (Drugs Exptl. Clin. Res. Vol. X(8-9) (1984) pages 587-597) and/or Rabasseda (Drugs of Today Vol. 32, No. 5 (1996) pages 365-384) is hereby withdrawn in view of applicant's amendments to the claims.

Maintained Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38, 47-48, 50-53, 49 plus 54-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (US patent 4,569,937) in view of Swingle et al. (Drugs Exptl. Clin. Res. Vol. X(8-9) (1984) pages 587-597) and/or Rabasseda (Drugs of Today Vol. 32, No. 5 (1996) pages 365-384) and further in view of Oshlack et al. US Pat. No. 5,472,712 (referred to as '712) or Oshlack et al. US Pat. No. 6,294,195 (referred to as '195) for the reasons set forth in the office action mailed 1/19/2005.

Please note the above rejection has been modified from the prior version to more clearly address applicant's amended and/or new claims as follows.

With regard to applicant's amendments to claims 38,49 and 50 and new claim 54 (ii), both Oshlack et al references teach sustained release carriers for oxycodone as pharmaceutically acceptable excipients. See the title of '195 and column 14 line 34 of '172.

'195 teaches combinations of oxycodone and salts thereof in column 6 lines 5-7,23 and 26 reading on new claims 63 (ii) and 65. '712 teaches combinations of oxycodone and salts thereof in claim 6 reading on new claim 63 (ii) and 65.

'712 teaches additional excipients in column 9, line 29, reading on new claim 54 (iii). '195 teaches additional excipients in column 9, line 56, reading on new claim 54 (iii).

'195 teaches a sustained release carrier for 24 hours in figure 1 and '712 teaches a sustain release of 24 hours in column 4 line 61, reading on new claims 55 and 62.

'195 teaches ethylcellulose (an alkylcellulose; elected species) in column 5 line 17 and '712 teaches ethylcellulose (an alkylcellulose; elected species) in column 3 line 60, reading on new claim 56.

Swingle et al teaches nimesulide is effective against arthritis (elected species) in the last paragraph on p 589, reading on claims 57,67 and 68.

'172 teaches 0.2 mm to 2.5 mm beads in column 9 lines 36-37 and '195 teaches 0.1 mm to 3 mm beads in column 5 lines 50-53, overlapping the ranges set forth in new claims 58 and 59 and the elected species.

'195 teaches a second drug may either be incorporated with an opioid in a controlled release matrix, reading on claim 61(ii) (elected species) or may be part of a controlled release coating, reading on new claims 60, 61 (i) and 66.

According to MPEP 2144.05, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Absent evidence to the

contrary, the concentration range set forth in claim 64 which varies over 5 orders of magnitude does not appear to be critical and thus does not constitute a patentable distinction from the prior art which as combined teaches a at least a ratio of oxycodone:nimesulide of 0.5 (see 200 mg nimesulide on p 275 paragraph bridging left and right column of Rabasseda and claim 9 of '195 reciting 400 mg oxycodone) which meets the claim criterion.

Response to Arguments

Applicant argues, see remarks entered 2/26/2008: (i) there is a lack of motivation to combine the Baker et al reference with the Swingle et al. or Rabasseda references because the combination would render the teaching of Baker et al unsatisfactory for its intended purpose; (ii) the examiner has not articulated what would prompt one skilled in the art to select nimesulide; (iii) there is no expectation of success in the combination.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

(i) Specifically, on p 6-8, 10-11 applicant argues that amended claim 38, by using the transitional term 'consisting', is closed to additional elements such as ibuprofen, which is required by Baker et al to provide synergistic analgesia when combined with oxycodone. Applicant asserts that nimesulide plus oxycodone would only be expected to provide additive analgesia, rendering the teaching of Baker et al unsatisfactory for its intended purpose.

While the examiner agrees that the presently claimed invention no longer reads

on a *combination* of oxycodone plus nimesulide plus ibuprofen, it is noted, the *substitution* of one component for another to yield predictable results represents a *prima facie* case of obviousness. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __, 2007 WL 1237837, at *12 (2007). Here, it would be obvious to make a simple substitution of nimesulide for ibuprofen because it was known at the time of filing that the both compounds represent art recognized equivalents for the same purpose (i.e. in vivo inhibition of induced prostaglandin synthesis providing the same antiinflammatory/analgesic relief). Therein nimesulide plus oxycodone would be expected provide at least additive analgesia, as admitted by applicant on p 10 line 5 of the remarks entered 2/26/2008.

And, in this vein, the examiner is unaware of any *per se* rule that necessarily limits the teachings of a reference to its preferred "synergistic" embodiments or teachings to certain locations within the document itself (e.g., the experimental results). To the contrary, a reference is good for all that it teaches to one of ordinary skill in the art, *In re Fritch*, 972 F.2d 1260, 1264, 23 USPQ2d 1780, 1782 (Fed. Cir. 1992), and is not limited to the particular invention described and to be protected by the patent, *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907, 225 USPQ 20, 25, (Fed. Cir.1985), the specific examples disclosed, *In re Fracalossi*, 681 F.2d 792, 794 n.1, 215 USPQ 569, 570 n.1 (CCPA 1982); *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976), or preferred embodiments. *In re Mills*, 470 F.2d 649, 651, 176 USPQ 196, 198 (CCPA 1972). Here, Baker et al. clearly teach the use of a general class of "analgesic combinations" to relieve pain and reduce side effects that would otherwise be

required by a larger dose of the analgesic alone (e.g., see Baker et al., column 1, lines 12-17, "More active analgesic combinations are in constant demand because they offer the attractive possibility of relieving pain with reduced dosages thereby diminishing the expected side effects and toxicity that would result from the otherwise required higher dosages"). The fact that Baker et al. classifies their results as "unexpected" only serves to support this conclusion. That is, Baker et al. must have been adequately interested in combining these analgesics "before" they realized the synergistic value of the combination (otherwise the result would not have been "unexpected" as purported). This is further supported by the express language of the patent wherein Baker et al. state, "[a] continuing goal is to be able to reduce the dosage of such narcotic analgesics by combining the them with non-addicting ingredients while still maintaining a high level of analgesia [i.e., whether the compounds exhibit a synergistic effect or not]" (e.g., see Baker et al., column 2, lines 5-8; see also more generally column 1 and 2 disclosing several examples of analgesic combinations including various NSAIDs including combinations that do *not* possess a synergistic effect; see especially column 1, lines 36-37, "there is no suggestion that the combination had a synergistic effect; see also lines 27-29, "Sunshine provides no evidence or suggestions of other than an additive analgesic effect for the combinations"). In other words, Baker et al teach *both* synergistic (with ibuprofen) as well as additive analgesia as beneficial, albeit the former more so.

Meanwhile, Swingle et al. and/or Rabasseda explicitly state that nimesulide is better than ibuprofen in terms of its potency/decreased side effects and Baker et al.

does *not* refute this position. Accordingly, a person of ordinary skill in the art would expect favorable results from this substitution. In addition, Baker et al. is not limited to ibuprofen as purported. For example, Baker et al. state in more general terms, "This patent [possibly attributing the effect to Sunshine et al] discloses that the analgesic effect of the combination of a selected NSAID and a selected narcotic analgesic is greater than for either alone" (e.g., see column 1, lines 22-25). It does not state, in contrast to Applicants' assertions, that any analgesic effect is only greater for ibuprofen. Whether substitution of another analgesic would be "unexpectedly" better (synergistic) is immaterial. The reference still provides ample basis to combine an NSAID with a selected narcotic analgesic. That is, the fact that "some" increased benefit would be obtained is enough.

Consequently, the intended purpose of Baker et al only requires a "reduced dosage" of the narcotic while still maintaining a "high level of analgesia" (e.g., see column 2, lines 5-10). That is exactly what nimesulide delivers. Thus, a person of ordinary skill in the art would expect to be able to "reduce the dosage" of the narcotic while still maintaining a "high level of analgesia" rendering the intended purpose set forth in the Baker et al. reference satisfactory.

(ii) Specifically in the first two paragraphs on p 9 of the remarks applicant argues the examiner has not provided adequate motivation to pick the Swingle et al. or Rabasseda references concerning nimesulide versus any other concerning other COX-2 inhibitors in development as of mid 1988.

In this vein, Swingle et al. and/or Rabasseda constitute the best available

references. The fact that other COX-2 inhibitors with similar activities were available at the same time does not eliminate the motivation to substitute nimesulide per Swingle et al. and/or Rabasseda for ibuprofen so as to provide a "reduced dosage" of narcotic while still maintaining a "high level of analgesia" yet with better gastrointestinal tolerance, as discussed in the last office action on p 6 last paragraph. Further motivation concerns the high potency of nimesulide which is discussed by Rabasseda on p 367 first full paragraph and is presented as very favorable therapeutic ratio in the abstract of Swingle et al and mentioned in the office action mailed 1/19/2005 p 4 penultimate paragraph. Said high potency stems from the fact that nimesulide not only has a high affinity and selectivity for cyclooxygenase 2, but it also acts as phosphodiesterase type IV inhibitor, has antiprotease effects against neutrophil elastase, cartilage collagenase and stromelysin, thus it is a multi-action compound with innovative antiinflammatory properties, as discussed by Rabasseda in the paragraph bridging the left and right columns on p 365.

(iii) Specifically in the third and fourth paragaph on p 9, applicant argues that the results of combining oxycodone with nimesulide would be unpredictable, especially with regard to generating a synergistic effect.

In this vein, the examiner agrees that a synergistic effect might not be expected by substituting nimesulide for ibuprofen in the combination of oxycodone plus ibuprofen based on the disclosure of Baker et al taken as a whole. However, as mentioned above in section (i), Baker et al also teaches beneficial additive analgesia may be achieved combining NSAIDs and opioids, such as oxycodone, so as to provide a "reduced

dosage" of narcotic while still maintaining a "high level of analgesia." Further, solely to rebut applicant's argument, evidence provided by Beaver (1984 Combination Analgesics. The American Journal of Medicine pp 38-53) and Beaver II (1992 Evaluation and Treatment of Chronic Pain Ch 29 Nonsteroidal antiinflammatory analgesics and their combinations with opioids) indicates the idea of combining NSAIDs with opioids was well established in the art at the time the presently claimed invention was made. In particular, according to Beaver on p 39 second paragraph, table II and the chapter title of Beaver II, various opioid combinations, including oxycodone, plus NSAIDs provide superior analgesia by the old idea of "cross-firing," that is enhancing efficacy by administering two drugs that produce the same effect by different mechanisms.

In conclusion, the Baker et al reference teaches more than just synergistic analgesia, as asserted by applicant, but also additive analgesia, both of which provide the intended purpose of a "reduced dosage" of narcotic while still maintaining a "high level of analgesia" by administration of opioids with NSAIDs. The potency and gastrointestinal tolerance of nimesulide provides ample motivation to substitute ibuprofen in the combination of oxycodone plus ibuprofen of Baker et al, which would predictably provide at least additive analgesia, an old idea well established in the art since at least 1984, as reflected in the Beaver references.

New Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38,47-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns "new matter."

This rejection is necessitated by Applicant's amendment to the claims.

Claim 38 has been amended to be drawn to a method for effectively treating pain in humans with an oral dosage consisting of nimesulide, oxycodone and a pharmaceutically acceptable excipient.

On p 6 of applicant's remarks entered 2/26/2008, applicant attempts to point to support on p 23 line 4 through p 30 line 15 of the specification as filed and in original claims 38,47,49 and 50-53.

It is noted however, claims 49 and 50-53 are not original. No support for said dosage form is found in original claims 38 or 47. Page 23 line 4 through p 30 line 15 discuss general combinations of opioids and COX2 inhibitors, with no mention of nimesulide plus oxycodone.

New claim 63 and dependent claims 64-66 are drawn to a method for effectively treating pain in humans with an oral dosage consisting of nimesulide plus oxycodone plus a pharmaceutically acceptable salt of oxycodone plus a pharmaceutically acceptable excipient.

On p 6 of applicant's remarks entered 2/26/2008, applicant attempts to point to support in original claims 38,47,49 and 50.

It is noted however, claims 47,49 and 50 are not original. No support for a pharmaceutically acceptable excipient is found in original claim 38.

New claim 54 includes the limitation of oxycodone or a pharmaceutically acceptable salt thereof in a sustained release form.

On p 6 of applicant's remarks entered 2/26/2008, applicant attempts to point to support on p 24 line 31 through p 25 line 31 of the specification as filed and in original claims 38, 49 and 50.

It is noted however, claims 49 and 50 are not original. No support for sustained release forms of oxycodone is found in original claim 38. Page 24 line 31 through p 25 line 15 discuss opioids with no mention of oxycodone.

New claim 55 is drawn to preserving a therapeutic effect of oxycodone for at least 12 hours. Applicant does not point to support.

New claim 56 includes various sustained release carriers, such as alkylcellulose. By dependence on claim 54 new claims 60 and 61 is drawn to oxycodone or a pharmaceutically acceptable salt thereof in a sustained release form wherin the sustained release carrier is either a coating or is incorporated into a matrix with oxycodone.

On p 6 of applicant's remarks entered 2/26/2008, applicant attempts to point to support on p 34 lines 11-23 and p 11 of the specification as filed.

It is noted however, while page 34 lines 11-23 discuss sustained release matrices, and p 11 discuses coatings, no mention is made of oxycodone in either passage.

Each of new claims 57,67 and 68 are drawn to various type of pain, such as stemming from arthritis.

On p 6 of applicant's remarks entered 2/26/2008, applicant attempts to point to support on p 22 lines 5-22 of the specification as filed.

It is noted however, while page 22 lines 5-22 discuss the types of pain set forth in claims 57,67 and 69, no mention is made of oxycodone or nimesulide.

Claims 58 and 59 are drawn to oral dosage particles in the range from about 0.1 mm to about 2.5 mm or 0.5 to about 2 mm, respectively.

On p 6 of applicant's remarks entered 2/26/2008, applicant attempts to point to support on p 25 lines 16-17 of the specification as filed.

It is noted however, while page 25 lines 16-17 discuss the requisite particle sizes, no mention is made of oxycodone or nimesulide, as set forth in claim 54 from which claim 58 and 59 depend.

New claim 60 is drawn to preserving a therapeutic effect of oxycodone for at least 12 hours. Applicant does not point to support.

New claim 62 is drawn to preserving a therapeutic effect of oxycodone for about 24 hours.

On p 6 of applicant's remarks entered 2/26/2008, applicant attempts to point to support on p 38 line 31 of the specification as filed.

It is noted however, page 38 line 31 discuss opioids with no mention of oxycodone.

The specification as originally filed provided no implicit or explicit support for the above limitations, especially concerning an oral dosage consisting of nimesulide, oxycodone and a pharmaceutically acceptable excipient.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1639